

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

_____)	
IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION)	MDL No. 1456
)	
_____)	Civil Action No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	Judge Patti B. Saris
ALL CLASS ACTIONS)	
)	
)	
_____)	

**TRACK 1 DEFENDANTS' MEMORANDUM IN OPPOSITION TO
CLASS PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT
ON DEFENDANTS' AFFIRMATIVE DEFENSES**

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The Track 1 Defendants ("Defendants") respectfully submit this response to Class Plaintiffs' Motion for Partial Summary Judgment on Defendants' Affirmative Defenses ("Plaintiffs' Motion on Affirmative Defenses").

INTRODUCTION

Plaintiffs' Motion was unnecessary: If the Plaintiffs had conferred with the Defendants as they were obliged to do by LR. 7.1 and informed the Defendants that they did not intend to try to resurrect the claims that have been dismissed or withdrawn, of course the Defendants would have agreed to withdraw their affirmative defenses against those claims; and if the Plaintiffs had conceded to the Defendants in the requisite (but omitted) conference of counsel that the Defendants did not bear the burden of proof on issues as to which that point was uncertain, of course the Defendants would have withdrawn those defenses that had been asserted in an abundance of caution and/or hopefully persuaded Plaintiffs that there was not sufficient evidence in the record as to particular class representatives to justify a wholesale elimination of defenses with respect to such representatives.¹ Indeed, if the Plaintiffs had convened the conference they were required to have convened, they likely would not have filed any motion addressed to affirmative defenses, as most defenses would have been withdrawn, and the few that would have remained would have been considered properly pleaded, supported by evidence, and not worth anyone's while to consider at this stage of the litigation. Plaintiffs' failure to comply with their obligations under LR. 7.1 warrants denial of their ill-conceived motion.

The Plaintiffs' disregard of LR. 56.1 likewise calls for denial of their motion. They move for summary judgment without including with their motion a statement of material facts not in dispute, thus disregarding an unequivocal requirement of LR. 56.1. The consequence of non-

¹ Concurrently with this joint submission, Defendant AstraZeneca is filing a separate memorandum addressing the inappropriate nature of Plaintiffs' broad effort to eliminate defenses in a factual vacuum.

compliance with that requirement is set forth with equal definiteness in the rule itself: "Failure to include such a statement constitutes grounds for denial of the motion."

The Plaintiffs' motion should be denied for the additional reason that it fails its essential purpose: Affirmative defenses against claims that remain in the case are properly asserted and supported by evidence. The Plaintiffs have obscured this point by failing to provide the requisite LR. 56.1 statement, but the propriety of the remaining affirmative defenses emerges on analysis, as shown below.

ARGUMENT

I. PLAINTIFFS' MOTION SHOULD BE DENIED FOR FAILURE TO COMPLY WITH LOCAL RULE 7.1

Plaintiffs' motion should be denied because they have failed to confer as required by the Rules of this Court. LR. 7.1(A)(2) provides that "[n]o motion shall be filed unless counsel certify that they conferred and have attempted in good faith to resolve or narrow the issue." This rule "forces the parties to present issues for resolution by the court *only* where agreement is not possible *after* good faith consultation." *Converse Inc. v. Reebok Int'l Ltd.*, 328 F. Supp. 2d 166, 170-71 (D. Mass. 2004) (noting the purpose of the rule is to "conserve judicial resources") (emphasis added). LR. 7.1(A)(2) is not optional, but applies to "*any* motion." *Hasbro, Inc. v. Serafino*, 168 F.R.D. 99, 101 (D. Mass. 1996). "It is not up to the Court to expend its energies when the parties have not sufficiently expended their own." *Id.* For this reason, failure to confer before filing a motion is grounds for denying that motion. *See id.* (denying motion to compel as "premature" when party filed motion before an impasse had been reached); *Boston Children Heart Found. v. Nadal Ginard*, No. CIV.A.93-12539-REK, 1995 WL 17015062 (D. Mass. 1995) (denying motion for costs based on "several independent reasons," including failure to comply with LR. 7.1(A)(2)); *see also Thompson ex rel. Thorp Family Charitable Remainder Unitrust v.*

Federico, 324 F. Supp. 2d 1152, 1171-72 (D. Or. 2004) (denying cross-motion for partial summary judgment when movant violated local rule by failing to confer when defendants were "ready and willing" to resolve the dispute).²

Here, good-faith conferral would have substantially narrowed the issues before the Court. This is not a case of a "motion certain to be opposed" in all respects. *See, e.g., Gerakaris v. Champagne*, 913 F. Supp. 646, 651 (D. Mass. 1996) (refusing to dismiss a motion "certain to be opposed" for failure to confer in advance). *But see Converse Inc.*, 328 F. Supp. 2d at 174 n.7 (noting that, when bad faith is present, "summary denial of [movant's] motion may not be wholly inappropriate even in light of [*Gerakaris*]"). Moreover, this is not a case in which Plaintiffs lacked time to confer. *See Converse Inc.*, 328 F. Supp. 2d at 174 (imposing sanctions when counsel's motion for contempt, "by virtue of their size and level of detail," were "not the result of a last minute 'fast break' to the courthouse."). Defendants filed responses to the Third Amended Master Consolidated Class Action Complaint in November 2005, giving Plaintiffs almost five months to confer before the deadline for summary judgment motions.³

A conference in this instance surely would have narrowed the issues Plaintiffs have now presented to the Court. Defendants have identified numerous affirmative defenses they are prepared to withdraw because the claims to which they are addressed have been dismissed by the Court, withdrawn by the Plaintiffs, or are now acknowledged by the Plaintiffs to be matters on

² Numerous other courts outside this District have denied motions based on violations of local rules requiring conferral in good faith prior to filing a motion. *See, e.g., Williams Island Synagogue, Inc. v. Aventura*, 329 F. Supp. 2d 1319, 1323 n.6 (S.D. Fla. 2004) (denying motion to strike notice of supplemental authority based on failure to certify that parties had conferred); *Wood v. Goldschmidt*, 962 F.2d 16 (table) (9th Cir. 1992) (affirming denial of motion to compel that failed to include certificate of conferral); *Rios v. Indiana Univ.*, No. 3:04-CV-276 RM, 2005 WL 1828767 (N.D. Ind. 2005) (denying motion to compel based on, *inter alia*, non-compliance with rule requiring certification before filing discovery motion).

³ The parties are in the process of stipulating that Track 1 Defendants need not respond to the Fourth Amended Master Consolidated Class Action Complaint (Mar. 1, 2006) (Docket Nos. 2171-2176) ("FAMCC"), given its similarity to the Third Amended Master Consolidated Class Action Complaint (Oct. 17, 2005) (Docket Nos. 1781-1787). This stipulation will be filed with the Court once completed. All citations herein will refer to the FAMCC.

which the Plaintiffs have the burden of proof; hence, the requisite conference of counsel would have largely – if not completely – obviated the need for the Plaintiffs’ motion.

A. Defenses Relating to Dismissed or Withdrawn Claims

Nowhere is the wastefulness of Plaintiffs’ motion more apparent than with respect to defenses against claims that have been dismissed by the Court or withdrawn by the Plaintiffs. Plaintiffs spend pages arguing that defenses against their RICO claims and antitrust claims should be eliminated because the claims have been dismissed by the Court. (*See, e.g.*, Pls.’ Mot. Partial Summ. J. re: Affirmative Defenses at 4, 6-7.) This was totally unnecessary. Based on Plaintiffs’ representation that these claims are no longer viable – and taking as granted that Plaintiffs do not intend to try to resurrect these claims – Defendants would have agreed if asked to withdraw defenses addressed to them.⁴ (*See* AstraZeneca Affirmative Defense Nos. 20, 21, 22, 23, 36, 37, 39, 40, 41, 42, and 43.)⁵

B. Defenses as to which Defendants Do Not Have Burden of Proof

Plaintiffs spend additional pages discussing defenses on which they now concede that they have the burden of proof. (*See* Pls.’ Mot. Partial Summ. J. re: Affirmative Defenses at 8, 10, 11, 14, 22, 26, 28.) Again, argument on these matters is pointless; the Defendants certainly may

⁴ Plaintiffs’ muddled approach to AstraZeneca Affirmative Defense No. 7 prevents Defendants from being able to respond at this time. Plaintiffs state this defense, regarding the *Noerr-Pennington* doctrine, should be dismissed because there are no antitrust claims and because “there is no evidence [of petitioning activity] in this case.” (Pls.’ Mot. Partial Summ. J. re: Affirmative Defenses at 6.) This is a defense, separate and distinct from the “government action” defense, aimed at plaintiffs’ claims “premised, in whole or in part, on alleged statements or conduct by [defendants] in judicial, legislative or administrative proceedings . . . or at any level of government.” (*See, e.g.*, BMS Affirmative Defense No. 6.) Yet, in Plaintiffs’ Memorandum In Support Of Motion For Partial Summary Judgment Against All Track 1 Defendants (“Plaintiffs’ Memorandum In Support of Summary Judgment”), Plaintiffs accuse Defendants of just such petitioning activity – namely “lobb[ying] the federal government to maintain AWP-based reimbursement for Part B drugs.” (Pls.’ Mem. Supp. Mot. Partial Summ. J. Against All Track 1 Defs. at 57-58.) Plaintiffs cannot have it both ways. If Plaintiffs wish to challenge Defendants’ lobbying activities, the *Noerr-Pennington* defense must remain, and Defendants are entitled either to exclude Plaintiffs’ evidence of their petitioning activity or to obtain a jury instruction regarding the appropriateness of such activity. If Plaintiffs are representing that they are not going to raise lobbying activity as an issue in the case, Defendants will consider withdrawing the defense.

⁵ For the convenience of the Court, Defendants have adopted the citation format used by Plaintiffs and shown in Exhibit A to their Motion. (*See* Pls.’ Mot. Partial Summ. J. re: Affirmative Defenses at 2 n.3.)

have agreed, depending on particular facts and law applicable to their respective class representatives, to withdraw these as affirmative defenses once the Plaintiffs had conceded that pleading them was unnecessary because Plaintiffs have the burden to disprove them. (*See* AstraZeneca Affirmative Defense Nos. 4, 6, 11, 14, 15, 18, 19, 25, 26, 27, 28, 29, 30, 31, 32, 33, 44, 45, 47, 50, 52, 53, 55.⁶)

Thus, most of the affirmative defenses addressed in the Plaintiffs' Motion likely would have been withdrawn if only the Plaintiffs had complied with LR. 7.1 and acknowledged in a conference what they have acknowledged in their papers – that they will not attempt to resurrect claims that have been dismissed or withdrawn, and that they bear the burden to disprove certain matters that had been pleaded as affirmative defenses owing to uncertainty as to who bore the burden. In such circumstances – where the moving party files motion papers without first conferring with opposing parties who stand "ready and willing" to narrow the issues in dispute – denial of the motion is appropriate. *Federico*, 324 F. Supp. 2d at 1171-72 (construing a rule similar to LR. 7.1 to deny summary judgment motion and noting that "[i]f the rule is to mean anything at all, at least the spirit of its substantive requirements must be met.").

II. PLAINTIFFS' MOTION SHOULD BE DENIED FOR FAILURE TO CARRY THEIR BURDEN ON SUMMARY JUDGMENT

As the parties moving for summary judgment, Plaintiffs must make a preliminary showing that no genuine issue of material fact exists. *See Cadle Co. v. Hayes*, 116 F.3d 957, 960 (1st Cir. 1997) (noting that "[t]he summary judgment machinery operates in two phases"). Both of the cases cited by the Plaintiffs for the erroneous proposition that they have no burden as

⁶ Plaintiffs attack several affirmative defenses in the abstract without attention to the circumstances in which they might be applicable. As indicated in AstraZeneca's supplemental brief, certain affirmative defenses need to be assessed in the context of specific allegations by specific class representatives against specific defendants. *See, e.g.,* AstraZeneca Pharmaceuticals LP's Supplemental Mem. Opp'n Pls.' Mot. for Partial Summ. J. re: Affirmative Defenses.

moving parties in fact stand for the opposite proposition. *See John Hancock Life Ins. Co. v. Abbott Labs.*, No. CIV.A.03-12501-DPW, 2005 WL 2323166, at *27 (D. Mass. 2005) (noting that "[a] party seeking summary judgment must make a preliminary showing that no genuine issue of material fact exists"); *Stevens v. Cedarrapids, Inc.*, No. CIV.04-89-B-W, 2006 WL 412192, at *4 (D. Me. 2006) (noting that "[a]s moving parties the [plaintiffs] must demonstrate an absence of evidence to support the nonmoving party's case").⁷

Here, Plaintiffs cannot carry their burden because they fail to include a Statement of Material Facts not in dispute as required by LR. 56.1, and they fail to show that no genuine issue of material fact exists as to the defenses Defendants are not prepared to withdraw.

A. Plaintiffs Cannot Carry Their Burden Because They Fail To Comply With Local Rule 56.1

Plaintiffs' motion should be denied for their failure to comply with LR. 56.1. The rule – and the remedy for its violation – could not be clearer:

Motions for summary judgment shall include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried, with page references to affidavits, depositions and other documentation. Failure to include such a statement constitutes grounds for denial of the motion.

LR. 56.1. "This Local Rule has teeth, and can be dispositive; parties ignore such rules 'at their own peril.'" *Barry v. Wing Memorial Hosp.*, 142 F. Supp. 2d 161, 163 n.1 (D. Mass. 2001) (noting "the importance of scrupulous compliance with D.Mass.R. 56.1") (internal citation omitted). Indeed, LR. 56.1 "goes to the heart of the summary judgment rule and the Supreme Court's opinion in *Celotex*." *Dale v. H.B. Smith Co, Inc.*, 910 F. Supp. 14, 20 (D. Mass. 1995) (denying motion and noting that 56.1 statement is necessary for a moving party to meet the

⁷ Plaintiffs cite *U.S. Liability Ins. Co. v. Selman*, 70 F.3d 684, 691 (1st Cir. 1995), for the proposition that the "usual rule" is that Defendants have the burden of proving affirmative defenses. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 3.) This is true but beside the point. As shown in text, the party moving for summary judgment also has a burden, a burden which Plaintiffs here fail to carry.

burden of "showing - that is, *pointing out to the district court*, that there is an absence of evidence to support the nonmoving party's case") (emphasis in original) (citing *Celotex v. Catrett*, 477 U.S. 317, 325 (1986)).

Here, Plaintiffs' disregard of LR. 56.1 prevents them from being able to carry their burden as the party moving for summary judgment. As the First Circuit recently noted, "whether the rule has been violated is . . . easily answered where the opponent fails to file any statement." *Alsina-Ortiz v. Laboy*, 400 F.3d 77, 80 (1st Cir. 2005) (construing rule similar to LR. 56.1 from another district court). This failure is especially striking because, as Plaintiffs claim at the outset of their motion, one of their goals is to identify defenses that "have some evidentiary support." (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 1.) Even though they do not offer such evidence or facts of their own, Plaintiffs variously state that they "contend" certain assertions are true or that they "challenge Defendants to present in their response any legal or evidentiary support." (*Id.* at 16, 27.) These assertions ring hollow when the Plaintiffs have not examined the factual record and stated to the Court the material facts as to which they say there is no dispute.

A summary judgment motion without a LR. 56.1 statement should be denied. *See, e.g., Abrazinski v. DuBois*, 876 F. Supp. 313, 319 (D. Mass. 1995) (noting that the lack of such a statement creates "both confusion for the court and possible prejudice to the opposing party"); *Dale*, 910 F. Supp. at 20 (denying motion for summary judgment for failure to include 56.1 statement). A party who neglects such local rules "must bear the onus of that neglect." *Ruiz Rivera v. Riley*, 209 F.3d 24, 28 (1st Cir. 2000) (finding that failing to file statement was "brazen disregard" of rule similar to LR. 56.1 and constituted "independently sufficient ground" to affirm judgment against offending party).

B. Summary Judgment is Not Appropriate Because Trial-Worthy Issues Of Fact Exist as to Remaining Affirmative Defenses

After eliminating defenses against claims that have been dismissed or withdrawn, and those as to which the Plaintiffs admit they bear the burden of proof, there remain certain affirmative defenses, all of which are properly pleaded and supported by sufficient evidence to warrant trial, including: (1) political question / separation of powers, (2) filed rate; (3) government action; (4) intervening / superseding conduct of third parties; (5) preemption; (6) statute of limitations and other defenses related to the passage of time; (7) failure to mitigate; (8) good faith and industry practice; and (9) compliance with regulations.

For the first four of these defenses, Plaintiffs assert that summary judgment is warranted based solely on rulings of the Court at the motion to dismiss stage. (*See* Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 5, 6, 7, 10.) This argument is entirely without merit. While a motion to dismiss assumes as true all factual allegations and reasonable inferences favorable to the plaintiffs, *see Patterson v. Omnipoint Communs., Inc.*, 122 F. Supp. 2d 222, 226 (D. Mass. 2000), the standard of review on a motion for summary judgment is "significantly different." *Ramirez-Averasturi v. Rivera Gonzalez*, No. CIV.A.03-2360, 2005 U.S. Dist. LEXIS 33001, at *25 n.4 (D.P.R. Sept. 8, 2005). Summary judgment, unlike dismissal for failure to state a claim, rests on a factual record – a record that Plaintiffs' motion entirely ignores. Indeed, Plaintiffs' argument would transform every denial of a motion to dismiss into a grant of summary judgment for the plaintiffs, which plainly is not so.

While an affirmative defense may be the basis for a motion to dismiss under Rule 12(b)(6), the defense survives denial of the motion. *See, e.g., Blackstone Realty LLC v. F.D.I.C.*, 244 F.3d 193, 199 (1st Cir. 2001) (vacating order of dismissal based on statute of frauds but recognizing that such a defense "might be successful either in a motion for summary judgment

filed after the close of discovery, or at trial."); *Rivera Colon v. Padilla Ferrer*, No. CIV.A.00-2351, 2003 U.S. Dist. LEXIS 2386, at *5 (D.P.R. Jan. 28, 2003) (denying motion to dismiss but noting that defendant could still pursue affirmative defense at trial or in motion for summary judgment). The rationale is simple: "affirmative defenses should be permitted an opportunity to be considered fully, even though they embrace a contention which was overruled when considered earlier as a face of a motion to dismiss." *Borrowdale v. First Nat'l Bank of Chicago*, No. 85-C-3742, 1985 WL 3082, at *1 (N.D. Ill. Oct. 8, 1985).⁸ Such is the case here.

1. Political Question / Separation of Powers

Plaintiffs seek summary judgment on the political question / separation of powers defense solely on the basis of the Court's denial at the motion to dismiss stage. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 5 (discussing AstraZeneca Affirmative Defense No. 2).) As noted *infra*, this argument fails on its face.

Ample evidence exists demonstrating the policy struggle between the Executive and Legislative branches in which it was determined that Medicare drug reimbursement should be based on the AWP in the publications and not physicians' cost, even though there was publicity surrounding so-called "mega-spreads." (See Mem. Supp. Joint Mot. Summ. J. at 2-9; *see also* Track 1 Track 1 Defs.' 56.1 Stmt.) Such evidence clearly shows that this defense is viable and must not be dismissed from the case.

⁸ Indeed, this Court has repeatedly acknowledged the lack of a factual record at the motion to dismiss stage and suggested that, upon a full factual record, a decision may be warranted at summary judgment. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 206 (D. Mass. 2004) (declining to dismiss consumer protection claims based on government knowledge and noting that "[w]ith a fuller record, including many of the documents cited by Defendants, the Court will revisit the issue at summary judgment."); *Commonwealth v. Mylan Labs.*, 357 F. Supp. 2d 314, 323 (D. Mass. 2005) (declining to dismiss common law fraud claim but noting that "[t]he reasonableness of any reliance is best left to a summary judgment record").

2. Filed-Rate

Plaintiffs contend that the defenses as to the filed rate doctrines ought to be dismissed because they, too, have been previously rejected. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 5 (discussing AstraZeneca Affirmative Defense No. 3).) As noted above, this rationale – here only two sentences – fails because the rejection of an argument at the motion to dismiss stage does not mandate the rejection of an argument on summary judgment or at trial.

This particular defense remains valid, and should be maintained. The Court ruled that “[t]he ‘filed rate’ doctrine is . . . inapplicable” because “[p]harmaceutical companies do not ‘file’ their AWP’s with any federal regulatory agency.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 191 (D. Mass. 2003). Even if the Court were correct in not granting dismissal on filed-rate grounds, the defense should be presented to the jury because a “filing” is not a *sine qua non* of the doctrine. The Supreme Court has recognized that the rate may be *either* (i) filed by a private party and merely “accepted” by the regulator *or* (ii) the rate may be “set”, “determine[d]” or “fixed” by the regulator itself based on market data. *Montana-Dakota Utils. Co. v. Northwestern Pub. Serv. Co.*, 341 U.S. 246, 251-52 (1951) (holding that “the right to a reasonable rate is the right to the rate which the Commission files or fixes, and . . . except for a review of the Commission’s orders, the courts can assume no right to a different one . . .”).

Most importantly for this case, the filed rate doctrine reaches a defendant’s unregulated, market-based activity “used by the government,” *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d at 178, where the plaintiff seeks to show how the defendant’s unregulated activity affected the regulated rates that *are* set by the government agency.⁹ Here, it is

⁹ See *Pub. Utility Dist. No. 1 v. Idacorp Inc.*, 379 F.3d 641, 651 (9th Cir. 2004) (applying filed-rate doctrine to bar suit for damages despite plaintiff’s argument that market-based rates had not been “filed” with FERC); *Transmission Agency of N. Cal. v. Sierra Pacific Power Co.*, 295 F.3d 918, 929-31 (9th Cir. 2002) (filed-rate doctrine applies to situation where agency sets rules for allocating transmission capacity and rates are not filed); *T & E Pastorino*

indisputable that the government uses AWP's to set drug reimbursement rates or "allowed amounts" for Medicare Part B providers.

3. Government Action

Plaintiffs claim that the defenses as to state action should to be dismissed because they have been previously rejected. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 6 (discussing BMS Affirmative Defense No. 5).) This argument again fails, for reasons noted above.

This particular defense remains valid, and should be maintained. The Court previously rejected Defendants' Rule 12(b)(6) motion based on the "government action" or "state action" doctrine because "plaintiffs do not claim that the harm they suffer stems from the AWP system as Congress has established it, but rather from defendants' fraudulent statements about their average wholesale prices." *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d at 191. In fact, Plaintiffs' "zero-by-statute" argument squarely puts in question whether or not the harm they claim is due to (i) Defendants' statements to the publications or (ii) as Defendants' contend, Congress' statutory incorporation of the publications' AWP's *knowing* of the range of spreads above "zero." (See Mem. Supp. Joint Mot. Summ. J. at 2, 14 (discussing "zero-by-statute" argument).) Again, Defendants intend to present evidence to the jury that Congress

Nursery v. Duke Energy Trading and Mktg., CV-02-2059, 2003 WL 22110491, at *4 (S.D. Cal. Aug. 27, 2003), *aff'd* 2005 WL 434485 (9th Cir. Feb. 25, 2005) (applying filed-rate doctrine to market based rate scheme where wholesale energy rates are not filed); *In re Cal. Wholesale Elec. Antitrust Litig.*, 244 F. Supp. 2d 1072, 1080 (S.D. Cal. 2003) ("[p]laintiff's complaint cannot be characterized as anything but a direct attack on rates or an attack on matters underlying wholesale electricity rates") (emphasis added), *aff'd*, 384 F.3d 756 (9th Cir. 2004); *Lifschultz Fast Freight, Inc. v. Consol. Freightways Corp. of Del.*, 805 F. Supp. 1277, 1294-97 (D.S.C. 1992) (filed rate doctrine bars claim that defendants' unfilled "fraudulent information" was incorporated into rates set by ICC), *aff'd* 998 F.2d 1009 (4th Cir. 1993); *Servais v. Kraft Foods, Inc.*, 631 N.W.2d 629, 633-635 (Wis. Ct. App. 2001) (USDA's reference to unfilled, open-market cheese prices to set regulated milk prices does not allow payers for milk to attack collaterally those milk prices; filed-rate doctrine applies to regulatory milk prices that depend on unregulated cheese prices), *aff'd*, 252 Wis.2d 145, 643 N.W.2d 92 (Wis. 2002); *Chandler v. Antham Ins. Cos., Inc.*, 8 S.W.3d 48, 50 (Ky. Ct. App. 1999) (filed rate doctrine barred claims that (i) "the unregulated portions of the [defendant] Antham [corporate] family charged [the] portions [of the family that were] regulated in Kentucky excessive fees" and (ii) "that those excessive fees were then fraudulently passed on to Kentucky rate-payers.").

knew of the existence of “mega-spreads” between the AWP’s and acquisition costs about which Plaintiffs complain and nevertheless mandated that those spreads continue – at least until recently, when the Medicare Modernization Act began adjusting payments to Medicare providers for services. (*See, e.g.*, Track 1 Defs.’ 56.1 Stmt. ¶¶ 25, 43-45, 89-90.) The impact of the government’s action on Plaintiffs’ alleged injuries thus remains a viable defense. *See, e.g., Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *Parker v. Brown*, 317 U.S. 341 (1943); *see also Lifschultz Fast Freight, Inc. v. Consol. Freightways Corp. of Del.*, 805 F. Supp. 1277, 1294-97 (D.S.C. 1992) (claim that defendants caused government regulator to set truck freight rates that drove plaintiff out of business deemed too remote to support proximate cause); *aff’d* 998 F.2d 1009 (4th Cir. 1993); *Cathay Pacific Airways, Ltd. v. Fly and See Travel, Inc.*, 3 F. Supp. 2d 443, 451-52 (S.D.N.Y. 1998) (plaintiffs’ voluntary decision not to challenge known overcharges by defendants under international air travel regulations, not the overcharges themselves, held the proximate cause of plaintiffs’ injuries).

4. Intervening/Superseding Conduct of Third parties

Plaintiffs likewise rely solely on language in the Court’s decision on the motion to dismiss to support their motion for summary judgment with respect to the defense that Plaintiffs’ claims are barred because Defendants’ conduct did not proximately cause Plaintiffs’ alleged injuries and/or because Plaintiffs’ alleged injuries resulting from the intervening or superseding conduct of third parties. (*See* Pls.’ Mot. Partial Summ. J. re: Affirmative Defenses at 10 (citing *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 207-08 (D. Mass. 2004).) As explained above, this reliance fails.

Moreover, Plaintiffs rely upon a portion of the Court’s motion to dismiss ruling wherein the Court was addressing Plaintiffs’ RICO claims, which are no longer in the case. While as to such claims the Court determined, on the pleadings alone, that Plaintiffs had adequately pleaded

causation in connection with Plaintiffs' then-existing civil RICO claims under 18 U.S.C §1962(c), the Court's discussion occurs in the context of a now-dismissed cause of action. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d at 207-08. Accordingly, that discussion simply cannot sustain Plaintiffs' motion for summary judgment with respect to claims at issue now.¹⁰

Finally, to the extent that facts evidencing the lack of causation between Defendant's alleged conduct and the injuries alleged by Plaintiffs can be viewed as an affirmative defense at all,¹¹ it remains viable in light of the record developed in this case. For example, for many – if not all – of the class representatives, the record demonstrates that Defendants did not make a single alleged misrepresentations directly to the person or entity. (*See, e.g.*, Newell Dep. Tr. (Nov. 15, 2005) at 148, attached as Ex. 1¹² (stating that neither she nor her husband had any contact or relationship with any drug manufacturer); Young Dep. Tr. (Nov. 9, 2005) at 61-62, 75-76 (stating that he had no knowledge as to how AWP was calculated, how it is used or who

¹⁰ Plaintiffs also point to a portion of the Court's decision citing Judge Stearns' motion to dismiss decision in the *Lupron* AWP litigation. (*See* Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 11.) This litigation, in fact, demonstrates why a decision on a motion to dismiss should not bar the ability to make similar arguments after discovery. Two years after his motion to dismiss decision, Judge Stearns observed upon settlement that "defendants have a powerful argument that the AWP was known to Congress and large insurers to be an artificial benchmark with no real market significance." *In re Lupron Mktg. and Sales Practices Litig.*, 228 F.R.D. 75, 97 (D. Mass. 2005) (noting that plaintiffs' "principal risks arise from . . . (3) the difficulty of deflecting defenses based on imputed knowledge that the AWP was subject to manipulation by defendants, as well as apparent government ratification of the defendants' conduct . . .").

¹¹ To the extent Plaintiffs' argument seek to impose on Defendants' the burden to demonstrate proximate causation, it is improper because proximate causation is an element of their claims on which Plaintiffs bear the burden. Indeed, many courts view an intervening or superseding cause defense merely as a challenge to a plaintiff's ability to carry its proximate causation burden. *See, e.g., Archer v. Warner*, 538 U.S. 314, 326 (2003) ("While the concept of proximate cause is somewhat amorphous, the common law is clear that certain intervening events – otherwise called 'superseding causes' – are sufficient to sever the causal nexus and cut off all liability.") (internal citations omitted); *Nat'l Mkt. Share, Inc. v. Sterling Nat'l Bank, Inc.*, 392 F.3d 520, 527 (2nd Cir. 2004) (holding that a defense that claims are barred as a result of an intervening cause is not an affirmative defense but merely an assertion that plaintiff cannot prove a necessary element of its claim); *E.I. du Pont de Nemours & Co. v. McCain*, 414 F.2d 369, 374 (5th Cir. 1969) ("The theory of new and independent cause is not an affirmative defense; it is but an element to be considered by the jury in determining the existence or non-existence of proximate cause.").

¹² All citations to "Ex. _" will refer to exhibits to the Declaration of Eric P. Christofferson Transmitting Documents Relied upon in Track 1 Defendants' Memorandum in Opposition to Class Plaintiffs' Motion for Partial Summary Judgment on Defendants' Affirmative Defenses, filed herewith.

used it and that he had no way of knowing who manufactured the drug his wife was administered), attached as Ex. 2.)¹³ The record also contains significant evidence that third-party publishers made independent judgments concerning what AWP to report in their publications. (See, e.g., Morgan Dep. Tr. (Jan. 11, 2005) at 230 (stating that the third-party pricing services ultimately determined which AWP to publish and the manufacturer does not control the AWP reported), attached as Ex. 9; see also Davies Dep. Tr. (Nov. 9, 2005) at 75 (stating that the pricing services set AWP), attached as Ex. 10.) Medicare and other payors, according to Plaintiffs, then relied on the reported prices, which allegedly caused reimbursements and co-payments to be inflated, which in turn caused injury to plaintiffs. Such an indirect causal chain may well be deemed too indirect to support Plaintiffs' cause of action. See, e.g., *Archer*, 538 U.S. at 326.

Similarly, in the Medicare Part B context, it is the prescribing doctor (or other health care provider), and *not* the Defendant manufacturers, that (i) decides to prescribe the pharmaceutical product; (ii) administers the pharmaceutical product; (iii) sets the charge for the pharmaceutical product that was administered; (iv) submits the claims for reimbursement to the Medicare carrier; and (iv) submits a bill to the Medicare beneficiary for any portion of the billed amount that was not covered by Medicare. (See, e.g., Report of Independent Expert Dr. Ernst R. Berndt

¹³ See also Howe Dep. Tr. (Nov. 16, 2005) at 90, 93-94 (stating that he never had any knowledge of the AWP of any drugs he was taking at any time, nor had Mr. Howe heard of any of the publications within which AWP was published), attached as Ex. 3; Aaronson Dep. Tr. (Nov. 17, 2005) at 46-47 (stating that his understanding of AWP, prior to reading the Complaint, was based solely on what his lawyers told him) attached as Ex. 4; Shepley Dep. Tr. (Nov. 11, 2005) at 75, 86-87 (stating that he does not know who the buyers or sellers of the drugs he was given were, and his drug preferences are not based upon price), attached as Ex. 5; Choice Dep. Tr. (Nov. 10, 2005) at 35-36, 41 (stating she does not know what medicine is supposed to cost but she assumes her Union does and she is trying to help them, and stating that she does not know what AWP is and that any belief that her payments were based on AWP came from her lawyers), attached as Ex. 6; Randle Dep. Tr. (Nov. 17, 2005) at 127-128, 135 (stating that all payments made by the fund were based on the Medicare-approved plan form, and "no other criteria was looked at," and also stating that he does not know who calculates AWP or generally how it is used, but that he assumes it was mostly the physicians who acted as providers and overcharged plan participants), attached as Ex. 7; Townsend Dep. Tr. (Nov. 15, 2005) at 82-83 (stating that he had no contact with anyone at AstraZeneca with respect to his treatment for cancer or use of Zoladex®), attached as Ex. 8.

to Judge Patti B. Saris (Feb. 9, 2005) (Docket No. 1384) ("Berndt Report") at 57-60, 99 (noting that the fact that the "prescriber is also the dispenser, impl[ies] that a potential conflict exists between physicians attempting to provide cost-effective and appropriate treatments for their patients, and physicians acting as dispensers of drugs receiving the benefits of any differential between the drug's acquisition costs, and reimbursement received from Medicare Part B or a commercial payor").)

Moreover, the prescribing doctor may set the "actual charge " for the pharmaceutical product at any level, including a level below AWP. *See* 42 C.F.R. § 405.517(b) (setting total Medicare reimbursement as "the *lower* of the *actual charge* on the Medicare claims for benefits or 95% of the national average wholesale price") (emphases added); *see also* FAMCC ¶ 160. When the doctor charges less than 95% of AWP, the Medicare beneficiary pays a co-payment equal to the doctor's "actual charge," not a higher co-payment amount based in any way on AWP. Accordingly, the health care provider's charging decision is a critical intervening cause of plaintiffs' alleged injury. *See, e.g., Valente v. Sofamor, S.N.C.*, 48 F. Supp. 2d 862 (E.D. Wis. 1999) (where patients lawsuit against manufacturers of medical device claimed that through advertising, promotional materials and other statements, the manufacturers had falsely represented the quality and features of their product, and had failed to disclose material information, all in violation of the state consumer fraud statute, court found that role of doctors/intermediaries precluded any "causal connection between the defendants' alleged conduct and any pecuniary loss suffered as a result of their continued back pain").

There is thus a significant factual record supporting the notion that numerous third-party acts, e.g., those of publishers or pricing information and physicians, played a substantial – if not a *sine qua non* – role in the reimbursements about which Plaintiffs complain.¹⁴

5. Preemption

Plaintiffs claim that the defenses as to preemption by the federal Medicare statute and ERISA should be dismissed based on the Court's May 2003 ruling on Defendants' initial motion to dismiss. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 7.) Again, this reliance fails for the general reasons noted above.

Plaintiffs overstate their case. Although the Court ruled that the Medicare statute did not preempt AWP-based state consumer law suits, it expressly recognized that “there may be some damage theories that are preempted (for example, whether the plans cover co-payments)” by the ERISA statute. *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d at 192; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 309 F. Supp. 2d 165, 177 (D. Mass. 2004) (holding that ERISA preempts AWP-based claims brought under the California Unfair Competition Law that “implicate[] heartland ERISA issues of administration of plans and fiduciary responsibility”).¹⁵ As this case has developed, it is now clear that the claims of Classes 1 and 2 very much involve the question of “whether plans cover co-payments.”

¹⁴ The government also plays a critical role in the causal chain in this case. Their role is discussed above and in detail in Defendants' motions for summary judgment. (*See, e.g.*, Mem. Supp. Summ. J. at 15-21.)

¹⁵ ERISA “shall supersede any and all State laws insofar as they may now or hereafter *relate to* any employee benefit plan.” 29 U.S.C. § 1144(a) (emphasis added). The words “relate to” apply broadly. *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 98 (1983); *Hampers v. W.R. Grace & Co.*, 202 F.3d 44, 49 (1st Cir. 2000). Accordingly, ERISA preemption “extends to any state cause of action that has a ‘connection or reference to’ an ERISA plan.” *Central States, Se. & Sw. Area Health & Welfare Fund v. Neurobehavioral Assocs.*, 53 F.3d 172, 174 (7th Cir. 1995) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47 (1987)). Each ERISA-qualified plan must issue a “summary plan description,” 29 U.S.C. § 1022(a), which is considered part of that plan. *See Barker v. Ceridian Corp.*, 122 F.3d 628, 633 (8th Cir. 1997). The summary plan description “shall include a description of: any cost-sharing provisions, including . . . copayment amounts for which the participant or beneficiary will be responsible . . . [and] whether, and under what circumstances, existing and new drugs are covered under the plan[.]” 29 C.F.R. § 2520.102-3(j)(3) (2002) (emphasis added).

Furthermore, the current posture of the case also demonstrates that the Class 1 and 2 claims are preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

a. ERISA Preemption

Plaintiffs assert claims in Counts VI and VII on behalf of employee benefit plans (the “Third-Party Payors”) that are explicitly alleged to be ERISA plans. (FAMCC ¶¶ 25-30, 596-601, 607, 612-13.) Indeed, one of the Class 2 representatives certified by the Court – Sheet Metal Workers National Health Fund – is a Taft-Hartley fund subject to ERISA. (*See id.* ¶ 30.) Similarly, many Class 1 members have supplemental insurance through Taft-Hartley benefit plans that are subject to ERISA. (*See, e.g., id.* ¶ 16.)

The claims of both Classes 1 and 2 implicate “damages theories” that will require the Court to determine “whether the plans cover co-payments.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d at 192. The Court has already seen in the proceedings over class certification that there is intense controversy over the extent of the Class 2 TPP’s coverage of beneficiary co-payments. Indeed, the threshold question of whether Class 1 members even have standing turns on whether their supplemental insurance covers all of their co-payments or only a portion.

This issue ultimately turns on the terms of plans that are governed by ERISA. Under federal law, each ERISA-qualified plan must issue a “summary plan description,” 29 U.S.C. § 1022(a), which is considered part of the ERISA plan. *See Barker v. Ceridian Corp.*, 122 F.3d 628, 633 (8th Cir. 1997). The summary plan description “shall” contain information about “eligibility for participation and benefits.” 29 U.S.C. § 1022(b). Department of Labor regulations further provide that the summary plan description “shall include a description of: any cost-sharing provisions, including premiums, deductibles, coinsurance, and copayment

amounts for which the participant or beneficiary will be responsible.” 29 C.F.R. § 2520.102-3(j)(3) (2002). Accordingly, the Court’s “inquiry must be directed to the plan,” *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 140 (1990), because the Court must consult the terms of the ERISA plans to determine whether the plan paid all of the beneficiary’s 20% co-pay or only a portion of that co-pay.¹⁶ Contrary to Plaintiffs’ unsupported assertions, the ERISA preemption affirmative defense remains valid.

b. *Buckman* Preemption

The present posture of the case also demonstrates that *Buckman* preemption is a viable defense. In that case, the Supreme Court held that state-law claims based on allegedly fraudulent statements made to the FDA to obtain approval for a medical device were preempted because “state-law fraud-on-the-FDA claims conflict with, and therefore are impliedly preempted by, federal law.” 531 U.S. at 348. The Supreme Court explained that such claims would unduly interfere with the FDA’s “statutorily required judgment” concerning the approval of devices and would “inevitably conflict with the FDA’s responsibility to police fraud consistent with the Administration’s judgment and objectives.” *Id.* at 349-50. However, in its 2003 decision, this Court ruled that *Buckman* did not apply to this case because: “Unlike the FDA in *Buckman*, CMS does not make a discretionary judgment with respect to the statutorily defined Medicare Part B reimbursement rates, and does not approve the AWP’s. Therefore, the decision of the pharmaceutical companies, not an agency action, is alleged to cause plaintiffs’ harm.” 263 F. Supp. 2d at 189.

¹⁶ See *Harris v. Harvard Pilgrim Health Care, Inc.*, 208 F.3d 274, 281 (1st Cir. 2000) (“ERISA will be found to preempt state-law claims if the trier of fact necessarily would be required to consult the ERISA plan to resolve the plaintiff’s claims.”); *Carlo v. Reed Rolled Thread Die Co.*, 49 F.3d 790, 794 (1st Cir. 1995) (“[B]ecause the ‘court’s inquiry must be directed to the plan,’ the [plaintiffs’] claims are preempted under the first test set forth in *Ingersoll-Rand*.”); *Vartanian v. Monsanto Co.*, 14 F.3d 697, 700 (1st Cir. 1994) (holding that state-law misrepresentation claim was preempted where plaintiff would have to allege, and court would have to find, that an ERISA plan exists).

At this stage of the litigation, however, the Court knows that HCFA did make a discretionary decision its 1991 regulation to base reimbursement on the lower of AWP or EAC (despite having initially proposed 85% of AWP) and the further discretionary decision never to conduct the surveys necessary to determine EAC. (*See* Mem. Supp. Joint Mot. Summ. J. at 4-5, 9.) The Court also knows that in 1997, Congress enacted the AWP-based reimbursement in a statute (despite the Administration's position that reimbursement should be based on actual acquisition costs); that in 2000 Congress barred any administrative changes to the reimbursement system pending further study; and that in 2003, after that further study, Congress decreed that reimbursement should be at 85% of AWP for 2004. (*Id.* at 6-9.) Moreover, both HCFA and Congress were fully informed at each of these decision points that there were substantial spreads between AWP and actual costs. (*Id.* at 4-9)

Thus, it is now clear that the AWP-based system was the product of several discretionary and informed decisions by HCFA and the Congress. Plaintiffs' claims, under the guise of state consumer protection statutes, seek to second-guess the policy decisions of the federal government. Moreover, through the HHS-OIG and the Department of Justice, the federal government has extensive authority to police Medicare fraud, and plaintiffs' state-law claims "inevitably conflict with [the federal agencies'] responsibility to police fraud consistent with [their] judgment and objectives." *Buckman*, 531 U.S. at 350. Under these circumstances, *Buckman* preemption applies.

6. Statute of Limitations and Others Based on the Passage of Time

Plaintiffs claim that the defense of statute of limitations is inappropriate because Defendants cannot establish a genuine issue of material fact as to these defenses based on the passage of time. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 15-17 (discussing

AstraZeneca Affirmative Defense No. 13).) Summary judgment for the Plaintiffs on this and other related defenses is inappropriate.

Plaintiffs are incorrect in asserting that Defendants hold the entire burden on this defense, and the Plaintiffs have failed to carry their burden on the issue, entitling the Defendants to summary judgment on the issue. (*See* Mem. Supp. Joint Mot. Summ. J. at 22-27.) Once it is established that the period between the purported injury and the plaintiffs' claims exceeds the limitation period, "[t]he burden is on the plaintiff to show facts sufficient to take the case out of the statute of limitations." *Collins v. Nuzzo*, 244 F.3d 246, 253 (1st Cir. 2001); *see also Zamboni v. Aladan Corp.*, 304 F. Supp. 2d 218, 224 (D. Mass. 2004) ("When the discovery rule is at issue, the plaintiff 'bears the burden of proving both an actual lack of causal knowledge and the objective reasonableness of that lack of knowledge.'" (quoting *Doe v. Creighton*, 439 Mass. 281, 283, 786 N.E.2d 1211 (2003))); *Compagnie de Reassurance d'Ile de France v. New England Reins. Corp.*, 944 F. Supp. 986, 1005 (D. Mass. 1996) (noting that plaintiffs bear the burden to prove fraudulent concealment).¹⁷ Here, there is no question that Plaintiffs bring suit for transactions that occurred well before the four-year limitations period; indeed, they make claims stretching back to 1991.

Yet, Plaintiffs do little more than "contend" that the limitations period ought to be tolled. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 16.) The only "evidence" they offer is a sentencing memorandum by the government in a criminal case against a manufacturer not in Track 1. (*Id.* at 16-17.) As if this weren't weak enough, Plaintiffs insert "[AstraZeneca]" five

¹⁷ Plaintiffs distort the law when they assert there is no statute of repose for consumer protection actions. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 17.) This is not true, even for the statute for which they cite it to be true. *See, e.g., Kozikowski v. Toll Bros., Inc.*, 354 F.3d 16, 21-22 (1st Cir. 2003) (holding that plaintiff's deceit claim under Mass. Gen. Laws ch. 93A is time-barred by the statute of repose); *Dicorato v. Procopio Const. Co.*, No. 993906F, 2002 WL 31677205, at *4 (Mass. Super. Ct. Oct. 31, 2002) (holding that certain "allegations of Chapter 93A violations . . . are governed by the statute of repose"). The cases Plaintiffs cite only describe the statute of repose; neither mentions consumer protection claims.

times into the text, even though the company's name appears nowhere in the memorandum.

(*Compare* Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 16-17 to Ex. B to Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 62-65.) This is not evidence that Plaintiffs lacked knowledge and that such lack of knowledge was objectively reasonable, as required to invoke the discovery rule. This is also not evidence of an active effort by the Defendants to conceal the existence of a cause of action, as required to evoke the fraudulent concealment burden. Plaintiffs fail to meet their burden of showing that no material issue of fact exists regarding the affirmative defense

Moreover, Plaintiffs cannot meet this burden. In fact, the undisputed record shows that the limitations period for reimbursements made before October 1997 should apply, and that the statute of limitations should not be tolled. (*See* Mem. Supp. Joint Mot. Summ. J. at 22-27.) In that Memorandum, Defendants identified specific record evidence that Plaintiffs knew, or should have known that AWP exceeded acquisition cost. (*Id.* at 24-25; *see also* Decl. of Eric M. Gaier, Ph.D. in Supp. Defs.' Mot. Summ. J. (Mar. 15, 2006) ¶¶ 4, 8-9.) There is also ample evidence of government knowledge and public records sufficient to show that the existence of a claim was not "fraudulently concealed," much less that the conduct was "self-concealing." (*See* Track 1 Defs.' 56.1 Stmt. *passim*.) Given this, Plaintiffs cannot show that summary judgment must be granted in their favor on these affirmative defenses; in fact, as shown in Defendants' Memorandum, the undisputed material record warrants the granting of summary judgment against Plaintiffs, not for them.¹⁸

¹⁸ The same analysis compels the rejection of Plaintiffs' arguments relating to the other defenses included in AstraZeneca Affirmative Defense No. 13, all of which relate to the effect of the passage of time. As Plaintiffs concede, laches bars a party from asserting a claim if the party "so unreasonably delayed in bringing the claim that it caused some injury or prejudice to the defendant." (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 18 (quoting cases).) Similarly, a claim can be waived by voluntary and intentional relinquishment of that right. (*Id.*) Given that there is an undisputed material fact that the parties *knew* that there was a gap between AWP and ASP years before they brought this suit, Plaintiffs' cannot argue that these defenses lack merit.

7. Failure to Mitigate

Plaintiffs do not dispute that failure to mitigate and consent or ratification are affirmative defenses. But they contend there are no genuine issues of material fact to be tried because defendants have not cited specific instances of failure to mitigate. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 20 (discussing AstraZeneca Affirmative Defense No. 49).)

In fact, the discovery record teems with examples of failure to mitigate, as illustrated by the conduct of named class representative Blue Cross Blue Shield of Massachusetts ("BCBSMA"). The Master Consolidated Class Complaint in this case was publicly filed on September 6, 2002. It echoed the allegations of numerous individual complaints that preceded it. BCBSMA, however, elected to continue reimbursing based on AWP. Some two years later, BCBSMA considered moving from AWP-based reimbursement to ASP-based reimbursement due to concerns about physician spread and AWP being "inflated" resulting in "overpayments." (See BCBSMA's "Analysis of CMS Average Wholesale Price Reform" (Feb. 7, 2004) ("BCBSMA Analysis") at 2, attached as Ex. 11.)

BCBSMA engaged in detailed financial analysis and found it could save over \$6 million a year by following CMS to ASP based reimbursement and increasing administration fees. (*Id.* at 7; DeVaux Dep. Tr. (Mar. 9, 2006) at 170-71, attached as Ex. 12.) But it decided to continue using AWP to reimburse physician clinics because of concerns that physicians would reject a change and possibly send their patients to hospitals, a more expensive setting for BCBSMA. (*Id.* at 175-78; BCBSMA Analysis at 7.) Indeed, BCBSMA has now gone even further, and is affirmatively moving *towards wider use of AWP* even while it is a named plaintiff in this case. Discovery has revealed that BCBSMA is currently moving towards using AWP in the hospital out patient department setting, because it will save money by moving from percentages of billed charges to AWP. (Cizauskas Dep. Tr. (Mar. 10, 2006) at 124-26, 140, attached as Ex. 13.)

BCBSMA is representative of the classes it represents in terms of its failure to mitigate, and consent or ratification. Indeed, as one BCBSMA witness conceded, AWP has remained the industry standard for reimbursement right through to the present day despite the wide circulation of the allegations reflected in this case and the availability of Medicare's alternative ASP benchmark. (Killion Dep. Tr. (Jan. 6, 2006) at 89:2-14, attached as Ex. 14.)

Plaintiffs also submit that affirmative defenses predicted on unjust enrichment and damages being speculative, remote and impossible to ascertain or allocate should be dismissed because these are not cognizable affirmative defenses. (*See* Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 23, 24.) Unjust enrichment is properly pled as an affirmative defense. *See Tillotson v. Tillotson*, No. 00-10198, 00-01032, 2000 WL 33951472, at *2 (Bankr. D. Vt. Nov. 20, 2000); *Dana Corp. v. Blue Cross & Blue Shield Mutual of Northern Ohio*, No. C87-7734, 1990 WL 264716, at *6 (N.D. Ohio Dec 14, 1990); *Los Angeles County Employees Ret. Ass'n v. Towers, Perrin, Forster & Crosby, Inc.*, No. CV 01-1351, 2002 WL 32919576, at *24 (C.D.Cal. June 20, 2002). *See also Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 412 F.3d 215, 234 n.7 (1st Cir. 2005) ("the elements of [an unjust enrichment] claim are unjust enrichment of one party and unjust detriment to the other party." (internal quotations omitted)).

Similarly, the speculative nature of damages here – even the Court's independent expert noted he was "unclear" to whether J-codes can be translated to NDC-level data – does ground an affirmative defense. *See Goss Int'l Corp. v. Tokyo Kikai Seisakusho, Ltd.*, 294 F. Supp. 2d 1027, 1033 (N.D. Iowa 2003) (denying motion for summary judgment on affirmative defense that damages are speculative and finding it to be an issue "best resolved at trial."). (*See also* Berndt Report at 105-06.)

8. Compliance with Regulation

Plaintiffs claim that the defense of compliance with applicable regulations is "vague and ambiguous." (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 27 (discussing AstraZeneca Affirmative Defense No. 12).) Plaintiffs' issue an ultimatum, as if they have the authority to compel the Defendants to do what they demand: "Plaintiffs challenge Defendants to present in their response any legal or evidentiary support in furtherance of this claimed defense. If none is presented, summary judgment barring this defense is appropriate." (*Id.*) This challenge is foolish.¹⁹

First, the law supports the defense. For example, Chapter 93A provides an affirmative defense: "[n]othing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States." Mass. Gen. Laws ch. 93A, § 3. Numerous courts have held that § 3 bars claims brought under Chapter 93A. *See, e.g., Cablevision of Boston, Inc. v. Public Improvement Comm'n of Boston*, 38 F. Supp. 2d 46, 61 (D. Mass. 1999) (for purposes of preliminary injunction, finding that section 3 exemption likely applied to electric utility whose conduct was approved by public commission); *Bierig v. Everett Square Plaza Assocs.*, 611 N.E.2d 720, 728 (Mass. App. Ct. 1993) (reversing summary judgment based on finding that the statute and regulations "established that the rents charged were permitted by the regulatory scheme").

Second, ample record evidence supports this defense. In their motion for summary judgment, Defendants have pointed out numerous specific facts to show that there is no regulatory or statutory basis for Plaintiffs' claim that AWP should equal ASP. (*See* Mem. Supp.

¹⁹ It is odd that Plaintiffs challenge the legal relevance of compliance with regulation when their own motion for summary judgment repeatedly claims that the lack of compliance with regulation is grounds for a finding of liability. (*See* Pls.' Mem. Supp. Mot. Partial Summ. J. against All Track 1 Defs. at 41-46, 120-125.)

Joint Mot. Summ. J. at 9-14.) The knowledge of the government has also been demonstrated in the Local Rule 56.1 Statement filed with the Court. (*See* Track 1 Defs.' 56.1 Stmt.) Despite their burden of proof at summary judgment, Plaintiffs simply ignore the voluminous undisputed record that support Defendants' position.

9. Good Faith and Established Industry Practice

Plaintiffs claim that good faith and conformity with established industry practice are not adequate defenses and should be dismissed. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 27-28 (discussing AstraZeneca Affirmative Defense No. 9).) They claim that: "[e]ssentially, Defendants allege that since everyone one [*sic*] was doing it, how could it be a violation of law?" (*Id.*) They ignore, however, the legal and evidentiary support for this defense. First, Plaintiffs ignore the numerous decisions holding that industry practice is relevant to a determination of unfairness and deceptiveness. *See, e.g., Commercial Union Ins. Co. v. Seven Provinces Ins. Co.*, 217 F.3d 33, 43-44 (1st Cir. 2000) (affirming judgment that reinsurer had engaged in unfair conduct under 93A based on, *inter alia*, expert testimony regarding "the traditional mores of the industry"); *James L. Miniters Ins. Agency, Inc. v. Ohio Indem. Co.*, 112 F.3d 1240, 1251 (1st Cir. 1997) (finding no 93A unfairness when insurer "adhered to the industry custom"); *Salisbury v. Monumental Life Ins. Co.*, 1 F. Supp. 2d 97, 103 (D. Mass. 1998).²⁰

Second, no credit is due Plaintiffs' assertion that no specific facts regarding industry practice on AWP exist in the record. (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at

²⁰ Plaintiffs cite a 28-year old opinion from a district court in Pennsylvania, *United States v. Standefer*, 452 F. Supp. 1178, 1188 (W.D. Pa. 1978), for the proposition that "industry practice [is] no defense to criminal prosecution." (Pls.' Mot. Partial Summ. J. re: Affirmative Defenses at 27-28.) Far from barring any such evidence from the case, though, the trial court in *Standefer* instructed the jury that industry practice could be considered in determining the motives and purposes of the defendant. *Id.* (noting that "[t]he most that can be asked is that the jury consider this along with the other evidence in the case in determining the defendant's intent and this the jury was permitted to do.").

28.) Indeed, the 56.1 Statement Defendants filed in support of their Motion for Summary Judgment recounts the litany of such evidence. (*See* Track 1 Defs.' 56.1 Stmt. *passim*.) Just by way of example, a 1984 HHS-OIG Report noted that "[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." (*Id.* ¶¶ 5-6.) In addition, a 1989 HHS-OIG report found that "the preponderance of the evidence demonstrate[es] that AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent." (*Id.* ¶ 15.) Plaintiffs cannot credibly assert that no specific facts exist concerning industry practice regarding AWP.

CONCLUSION

For all of the foregoing reasons, Class Plaintiffs' Motion for Partial Summary Judgment on Defendants' Affirmative Defenses should be denied.

Respectfully submitted,

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Dated: April 7, 2006

CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson_____
Eric P. Christofferson